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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,159	01/20/2004	Biten K. Kathrani	END-5255	2562

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EXAMINER	
STIGELL, THEODORE J	
ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
06/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/761,159	KATHRANI ET AL.	
	Examiner	Art Unit	
	THEODORE J. STIGELL	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24,26 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24,26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/11/2008 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-7, 10-11, 15-16, 18, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Burney et al. (5,800,389). Burney discloses a medical device (10) comprising a first elongate member (20), a second elongate member (11) having an open proximal end and an open distal end (13), wherein the first member is releasably attachable to the second member to provide a continuous fluid passageway, wherein the outer diameter of the first elongate member is greater than the internal diameter of the second member, and wherein the distal end of the first member is positioned intermediate the proximal and distal ends of the second member upon attachment of the

two members (see figure 4, element 13 extends past distal end 21), wherein the first member has a closed, pointed, non-bifurcated distal tip (30), wherein the first member comprises a relatively rigid body portion (40) and a relatively flexible distal end portion (20), wherein the first member can be considered a hollow cannula extension, and the second member can be considered a cannula, wherein the first member comprises at least one side opening (24) extending through a wall thereof and spaced proximally of the distal end and distally from the proximal end (Figure 4 clearly shows that the opening is spaced from the proximal and distal ends) and a sleeve (41), and wherein at least one of the first and second members comprise a non-circular cross section at least partially somewhere along the length of the device.

Claims 1-2, 4-11, 13, 15-16, 18-22, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Liegner (4,803,999). Liegner discloses a medical device (10) for providing access to an internal space in a patient, the device comprising a first elongate member (12,17) having a proximal end, a distal end, an outer diameter, and an internal lumen, a second elongate member (14) having an open proximal end, an open distal end, and an internal lumen having an internal diameter and providing a passageway extending therethrough, wherein the first member is releasably attachable to the second member to provide a generally continuous fluid passageway, wherein the outer diameter of the first elongate member is greater than the internal diameter of the internal lumen of the second elongate member, and such that the distal end of the first member is positioned intermediate the proximal and distal ends of the second member upon attachment of the second member to the first member (see figure 2), wherein at

least the first member has an opening (at 22) spaced from the proximal and distal ends, wherein the first member has an open, pointed, non-bifurcated distal tip (15), further comprising a cap (18) releasably attachable to either member, wherein the second member has a beveled distal end (27), and further comprising a sleeve (30).

Claims 1-2, 5-16, 19-22, and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Dorsey (5,505,710). Dorsey discloses a medical device (see at least Figures 1-3 and 7-10) comprising a first member (50, 160,260), a second member (22,127,227), wherein the first member is releasably attachable to the second member and has a larger diameter, and wherein the second member can be inserted past the first member so that the end of the first member lies between the ends of the second member, wherein the first and second members include openings (28, 164, 264) spaced away from the ends of the members, wherein the first member has an open tip, further comprising a cap (14, 114, 214) and a sleeve (30, 130, 230), and wherein the second member comprises a beveled distal end. The examiner notes that the system is designed for suction and therefore must include a vacuum source.

Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Akiyama (3,896,810). Akiyama discloses an assembly comprising a vacuum device (28, 32) for providing an operative space within a patient, and a multi-component device for providing access from the vacuum to a point within the patient, the multi-component device comprising a detachable first (15) and second (10) members, the first member for providing a first portion (lumen of 15) and the second member for providing a second portion (lumen of 10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. (5,800,389), Liegner (4,803,999), or Dorsey (5,505,710). Burney, Liegner, and Dorsey disclose the claimed invention except for using a transparent wall. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use transparent material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).*

Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. (5,800,389), Liegner (4,803,999), or Dorsey (5,505,710) in view of

Sommerich (6,916,310). Burney, Liegner, and Dorsey disclose all of the limitations recited in the independent claims but fail to disclose the use of a medicinal coating on the sleeve. Sommerich teaches a medical sleeve that comprises a sealing surface and is adapted to provide a substantially airtight seal between the patient and an inserted tube. (See Figure 2) The sleeve is coated with an antibacterial substance (See Claim 25). To one of ordinary skill in the art at the time of the invention, it would have been obvious to modify the disclosure of Burney, Liegner, and Dorsey with the teachings of Sommerich to provide a sleeve with a medicinal coating to reduce the risk of infection.

Response to Arguments

Applicant's arguments filed 6/11/2008 have been fully considered but they are not persuasive.

In response to the applicant's argument that Burney and Liegner do not teach the subject matter of claim 11, the examiner respectfully disagrees. Burney clearly shows in Figure 4 that the opening (24) is spaced from the distal end and the proximal end. Liegner clearly shows in Figure 3 an opening (at 22) that is spaced from the distal end and proximal end.

In response to the applicant's argument that Akiyama does not teach a vacuum device "for providing an operative space within a patient", the examiner respectfully disagrees. The examiner notes that the limitation of "providing an operative space within a patient" is a functional limitation. The examiner maintains that the vacuum device of Akiyama is capable of performing this function by inserting the device in the patient.

In response to the applicant's argument that Akiyama does not teach first and second members for providing first and second portions of a passageway, the examiner respectfully disagrees. The examiner notes that identified members 10 and 15 are tubular and therefore each have a passageway. The lumen of 10 is a first portion and the lumen of 15 is the second portion.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763